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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/825,423 | 04/03/2001 | Patricia C. Weber | ID01152 | 2057 |
| 24265 | 7590 | 12/12/2006 | EXAMINER | |
| SCHERING-PLOUGH CORPORATION PATENT DEPARTMENT (K-6-1, 1990) 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033-0530 | | | STEADMAN, DAVID J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1656 | |

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary

Application No.

09/825,423

Applicant(s)

WEBER ET AL.

Examiner

David J. Steadman

Art Unit

1656

All participants (applicant, applicant's representative, PTO personnel):

(1) David J. Steadman.

(3) _____.

(2) Melodie W. Henderson.

(4) _____.

Date of Interview: 28 November 2006.

Type: a) ☒ Telephonic b) ☐ Video Conference

c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☒ Yes e) ☐ No.

If Yes, brief description: Draft of proposed claim amendment.

Claim(s) discussed: Claims 9, 11, and 21-22.

Identification of prior art discussed: NONE.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

DAVID J. STEADMAN, PH.D.
PRIMARY EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The proposed claim amendment was addressed. The examiner acknowledged the amendment to claim 11 to recite space group and unit cell dimensions and suggested inserting "of SEQ ID NO:17" following "two molecules" in line 4 of the amended claim to clarify that the "two molecules" are SEQ ID NO:17. Regarding claim 9, the examiner suggested claim language to clarify the claim as follows: An isolated polypeptide consisting of SEQ ID NO:3, SEQ ID NO:5, or SEQ ID NO:6, except the polypeptide has a single amino acid substitution at Asp73 or Arg81, and wherein the substitution is with a nonpolar amino acid. The examiner suggested clarifying claims 21-22 using similar claim language. The examiner noted that the support for claim 22 as set forth in the remarks section of the proposed amendment would need to be further analyzed. The examiner also noted that further consideration of the claims would be required upon receipt of an amendment.

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FACSIMILE TRANSMITTAL SHEET

TO:

DAVID J. STEADMAN,
EXAMINER
USPTO, COMMISSIONER
FOR PATENTS

FAX NUMBER:

9-1-571-273-0942

FROM:

Melodie W. Henderson

PHONE NUMBER:

(908) 298-7482

TOTAL NO. OF PAGES INCLUDING COVER

6

DATE

November 27, 2006

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Examiner: DAVID J. STEADMAN**Application No. 09/825,423****In re Application of Patricia C. Weber *et al.*****Filed: 04-03-2001****Group Art Unit: 1656****Attorney Docket No.: ID01152**

Dear Examiner Weber:

For the telephone discussion to be held on November 28, 2006 at 9:00 a.m., transmitted herewith are:

- Fax Cover Sheet - 1 page
- Response - DRAFT - FOR DISCUSSION PURPOSES ONLY - 5 pages

Melodie W. Henderson
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 09/825,423 Confirmation No. 2057
Applicant : Patricia C. Weber *et al.*
Filed : April 3, 2001
TC/A.U. : 1656
Examiner : Steadman, David J.
Docket No. : ID01152
Customer No. : 24265

November 27, 2006

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE

This is in response to the Final Rejection mailed October 3, 2006, for which a response is due January 3, 2007.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 4 of this paper.

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Reply to Office Action of October 3, 2006

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Amendment to the Claims

The listing of claims will replace all prior versions of claims in the application:

Claim 1 (previously presented): An isolated polypeptide defined by the amino acid sequence set forth in SEQ ID NO: 3, SEQ ID NO: 5, SEQ ID NO: 6, or SEQ ID NO: 17.

Claim 2 (previously presented): The polypeptide of claim 1, defined by the amino acid sequence set forth in SEQ ID NO: 17.

Claim 3 (previously presented): The polypeptide of claim 1, defined by the amino acid sequence set forth in SEQ ID NO: 3.

Claim 4-6 (cancelled).

Claim 7 (previously presented): The polypeptide of claim 1, defined by the amino acid sequence set forth in SEQ ID NO: 5.

Claim 8 (previously presented): The polypeptide of claim 1, defined by the amino acid sequence set forth in SEQ ID NO: 6.

Claim 9 (currently amended): An isolated polypeptide defined by a variant of the amino acid sequence set forth in SEQ ID NO: 3, SEQ ID NO: 5, and SEQ ID NO: 6, ~~wherein the variant consists of~~ with a single amino acid substitution at Asp 73 or Arg 81, and wherein the substitution is a nonpolar amino acid.

Claim 10 (cancelled)

Claim 11 (currently amended): A ~~crystalline~~ composition, comprising a protein crystal of an isolated polypeptide defined by the amino acid sequence set forth in SEQ ID NO: 17, wherein the crystal has space group P21 and unit cell dimensions of a=34.8 Å, b=67.1 Å, c=58.4 Å, α=90°.

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of SEQ ID NO: 17
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$\beta=101.3^\circ$, $\gamma=90^\circ$ with two molecules in the asymmetric unit and the structural coordinates set forth in Table 5.

Claims 12-20 (cancelled).

Claim 21 (currently amended): An isolated polypeptide defined by a variant of the amino acid sequence set forth in SEQ ID NO: 3, SEQ ID NO: 5, or SEQ ID NO: 6[, wherein the variant consists of] with a single amino acid substitution at Asp 73 or Arg 81, and wherein the substitution at Asp 73 is lysine or arginine and the substitution at Arg 81 is glutamic acid or aspartic acid.

Claim 22 (currently amended): An isolated polypeptide defined by a variant of the amino acid sequence set forth in SEQ ID NO: 5, wherein [the variant consists of a substitution of] the amino acids at positions 255-258 are replaced with SEQ ID NO: 7, 8, 9, 10, 11, 12, 13, or 14.

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REMARKS

STATUS OF THE CLAIMS

Upon entry of the foregoing amendment, Claims 1-3, 7-9, 11 and 18 will be pending.

Claims 9, 11, 21 and 22 are amended to clarify the meaning of the claims. Support for the amendment to Claim 11 is found in the originally filed specification at p. 42-45, examples 14-16. The support for the amendment to Claim 22 is described in detail below, in the Section entitled "CLAIM REJECTIONS - 35 U.S.C. § 112, First Paragraph".

CLAIM REJECTIONS - 35 USC §112, Second Paragraph

Claims 9 and 21-22 are rejected for indefiniteness, as being confusing in the use of the transitional phrase "consists of" with respect to the amino acid sequence of the claimed variant. Applicant agrees with the interpretation of these claims as applied in the Office Action, and believes the amended claims are consistent with this interpretation. Thus, Applicant respectfully requests withdrawal of this rejection.

CLAIM REJECTIONS - 35 U.S.C. § 112, First Paragraph

Claims 22 stands rejected under 35 U.S.C. § 112, first paragraph, as containing new matter because the claimed polypeptide is allegedly not supported by the specification. As requested in the Office Action, the following paragraph sets forth a detailed explanation of where support for this claim is found in the originally filed specification.

On page 11, lines 14-30, the specification describes the preparation of fragments comprising subdomain II in which a deletion of the anti-parallel β loop at positions 431 to 451 of SEQ ID NO:1 is replaced by insertions of specific sequences (i.e., see lines 17-19 and 26-30). SEQ ID NO:1 is described as the sequence for HCV -1a NS3 at p. 26, lines 25-26. On page 6, lines 18-21, the specification also describes SEQ ID NO:5 as being the sequence of a subdomain I,II construct containing amino acid residues 181-481 from HCV -1a NS3 (i.e., SEQ ID NO:1) in which 431 to 451 (the anti-parallel β loop) has been replaced by SDGK (SEQ ID NO:2). A comparison of SEQ ID NO:1 and SEQ ID NO:5 shows that the amino acid sequence between positions 181-430 and 452-481 of SEQ ID NO:1 is the same as the amino acid sequence between

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positions 5-254 and 259-288 of SEQ ID NO:5, respectively. Thus, positions 255-258 in SEQ ID NO:5 represent the insertion of SDGK (SEQ ID NO:2) at the site in SEQ ID NO:1 where the β loop is deleted (i.e., positions 431-451). Page 11, lines 26-30 teach that the deleted β loop could be replaced by other specified sequences. Thus, in other subdomain I,II constructs taught by the specification, SDGK at positions 255-258 in SEQ ID NO:5 would be replaced by SEQ ID NO:7, 8, 9, 10, 11, 12, 13 or 14.

In view of the foregoing, Applicant believes that claim 22 is adequately described in the specification as filed, and respectfully requests withdrawal of this new matter rejection.

Claim 11 stands rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description and enablement requirements. Applicant requests withdrawal of this rejection in view of the amended claim, which is directed to the single species that the Office Action states is described in, and enabled by, the specification. .

CONCLUSION

It is believed that the foregoing amendments and remarks place this application in condition for allowance. The Examiner is requested to contact the undersigned attorney if any additional questions or concerns arise.

Respectfully submitted,

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